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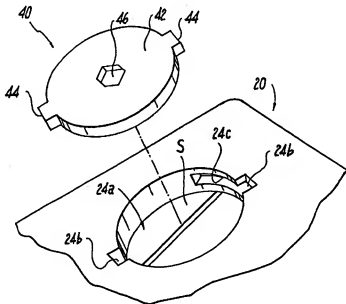
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[Continued on next page]

(54) Title: BONE FIXATION SYSTEM AND METHOD



(57) Abstract: A bone fixation system is provided which includes an elongated plate body having a central longitudinal axis, opposed upper and lower surfaces and an outer periphery defined in part by opposed first and second lateral edges, the elongated plate body including at least one through-bore formed between the opposed upper and lower surfaces for receiving at least one respective bone fastener to secure the elongated plate body to a bone repair site; and, a lockable cover engageable with the upper surface of the elongated plate body to cover at least a portion of the at least one through-bore formed therein. The elongated plate body and the cover include corresponding dovetail structures for the engagement with each other.

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- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

BONE FIXATION SYSTEM AND METHOD

5 CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 60/281,715, filed April 5, 2001, the entire contents of which are incorporated by reference herein.

10 FIELD OF THE INVENTION

The present invention relates to an implantable fixation system for the surgical repair of bone defects. Although the subject of the invention can be adapted for use with a variety of different bones in a variety of different locations, it is especially useful for anterior or lateral treatment of spinal disorders and more particularly, to a
15 fixation system including a cover for use in the anterior treatment of the lumbar and thoracic spine.

BACKGROUND OF THE INVENTION

The spinal column is a complex system of bones and connective tissue which protects critical elements of the nervous system. Closely associated with the bony
20 portion of the spine are soft tissues such as arteries, veins, nerves, etc. For example, on the anterior portion of the spine, arteries such as the aorta, anterior spinal arteries, anterior radicular arteries, dorsal branches of posterior intercostal arteries, posterior intercostal arteries, etc., are closely associated with the spine.

Conventional methods of spinal fusion frequently rely on the use of, e.g., bone
25 screws to attach a fusion plate to components of the spine. A problem with these methods, for example, especially with anterior spinal fusion, is that the screw used to affix the plate to the spine tends to back out and engage adjacent soft tissues such as,

e.g., vascular tissues. Another problem of the prior art is that the fusion plate itself is located on the surface of the bone it is affixed to. Thus, for example, the edges of the fusion plate may engage the adjacent soft tissues. Engagement of the bone screw and/or fusion plate with adjacent soft tissues can result in clinical outcomes ranging from, e.g., minor discomfort, localized pain, minor internal bleeding, major internal bleeding, paralysis, etc. Therefore, there is a need for a bone fixation system that overcomes the limitations of the prior art.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a bone fixation system. In one preferred embodiment, the system comprises a bone fixation plate which includes an elongated plate body having a central longitudinal axis, opposed upper and lower surfaces and an outer periphery. The outer periphery of the plate body is defined in part by opposed first and second lateral edges. The opposed first and second lateral edges are preferably curved inward toward the longitudinal axis in a medial region of the plate. Alternately, other plate configurations are envisioned. In certain embodiments disclosed herein, the opposed first and second lateral edges have disposed thereon a dovetail region, the dovetail region allowing mating and engagement of the plate with a corresponding cover. In another embodiment disclosed herein, the first and second edges have disposed thereon protrusions and/or groves to fit, snap, engage, etc. with corresponding features of a corresponding cover.

The bone fixation system of the present invention further comprises a cover for covering the plate. The cover is configured to be able to engage, i.e., mate, with the elongated plate. In one embodiment, the cover abuts a ledge on the top of the plate. The cover can be configured to have appropriate features such as, for example,

- protrusions, grooves, dovetail features, etc., so that the cover can affixedly fit, snap, mate, etc., with corresponding features on the plate. In this manner, the cover for the plate can be engaged with the plate in such a manner as to cover the anterior or top surface of the plate. When utilized in an appropriate surgical procedure, the fixation
- 5 device system disclosed herein prevents the "backing out" of the, e.g., screws or other devices used to attach the plate to the bone or bones. The cover for the plate of the fixation device system, when engaged with the plate, also serves to reduce the damage that may result from the contacting of any overlying soft tissue(s), e.g., vasculature, with the implanted fixation device system because of the "backing out" of the screws.
- 10 Other advantages provided by use of the fixation plate system disclosed herein will be apparent to those of skill in the art in view of the specification and the various figures described herein.

- In another embodiment disclosed herein, there is provided a method of using the disclosed fixation system. The method includes the step of making an
- 15 appropriately configured recess into the bone or bones intended to receive the fixation system. In this way a portion or all of the fixation system can be contained within the appropriately configured recess such that the region or regions exposed above the surface of the receiving bone are minimized.

BRIEF DESCRIPTION OF THE DRAWINGS

- 20 Preferred embodiments are described herein with reference to the drawings, wherein FIG. 1 is a perspective view of one embodiment of the fixation system described herein showing one possible method of engaging the cover portion with the plate portion. In this embodiment, the cover is slidably engaged with appropriate regions provided on the periphery of the plate. FIG. 1a shows the embodiment

described by FIG. 1 with the cover in place.

FIG. 2 is a perspective view of another embodiment of the fixation system described herein. FIG. 2a shows the embodiment described by FIG. 2 with the cover in place.

5 FIG. 3 is a perspective view of yet another embodiment of the fixation system described herein. In this embodiment, the cover is pressed onto the anterior surface of the corresponding plate. FIG. 3a shows the embodiment described by FIG. 3 with the cover in place.

FIG. 4 is a perspective view of another embodiment of the fixation system
10 described herein. In this embodiment, protrusions are provided on the inside surface of the cover to fit, snap, etc., into the corresponding screw holes of the plate. FIG. 4a shows the embodiment described by FIG. 4 with the cover in place.

FIG. 5 is a perspective view of another embodiment of the fixation system described herein. FIG. 5a is an enlarged sectional view of the circled portion of the
15 plate shown in FIG. 5b. FIG. 5c is cross sectional view of the embodiment described by FIG. 5.

FIG. 6 is an exploded partial perspective view of yet another embodiment of the fixation system described herein.

FIG. 7 is an exploded partial perspective view of yet another embodiment of
20 the fixation system described herein.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The spinal fixation system described herein is intended to be placed between adjacent vertebrae or bone treatment site in an attempt, e.g., to correct a debilitating condition. The fixation system is especially suitable for procedures where it would be

desirable to affix the anterior portion of the spine. However, it is of course entirely suitable to applications involving the lateral spine as well as other bony sites in a body. In humans, the system may be used predominately in the lumbar and thoracic regions of the spine, but, is adaptable for use in the cervical spine and other regions of the body as well. When in place, the fixation system maintains the proper spacing between adjacent vertebrae and serves to minimize the engagement of the implanted device with adjacent soft tissues.

The bone fixation device system of the invention may be formed of any biocompatible material or combination of such materials. "Biocompatible" means that no serious systemic toxicity is caused by the presence of the material in a living system. It is contemplated that biocompatible materials may cause some clinically acceptable amounts of toxicity including irritation and/or other adverse reactions in certain individuals. For example, the material described in U.S. Pat. No. 5,899,939, the contents of which are incorporated herein, may be entirely suitable for fabricating all or a portion of the system described herein.

The bone fixation device system may also be fabricated from any of the various biocompatible polymers. Examples of biocompatible polymers suitable for use herein would include bioabsorbable polymeric materials such as, for example, polymers and/or copolymers containing any of the following polymerizable monomers, epsilon-caprolactone, glycolide, trimethylene carbonates, tetramethylene carbonates, dimethyl trimethylene carbonates, dioxanones, dioxepanones, absorbable cyclic amides; absorbable cyclic ether-esters derived from crown ethers; hydroxyacids capable of esterification, including both alpha hydroxyacids (such as glycolic acid and lactic acid) and beta hydroxyacids (such as beta hydroxybutyric acid and gamma

hydroxyvaleric acid); polyalkyl ethers (such as polyethylene glycol and polypropylene glycol and combinations thereof), etc. Of course non-bioabsorbable polymers that are biocompatible such as, for example, polytetrafluoroethylene, polyethylene, etc., would also be suitable for fabricating any or all of the components of the fixation device system described herein.

The fixation device system may also be fabricated from metallic materials used in the fabrication of implantable devices, for example, surgical stainless steel, titanium, titanium alloys, shape memory alloys (especially for the cover member where its shape memory capability can be used to provide a more secure engagement with the base plate), etc. Carbon fibers can also be utilized for the fabrication of the base plate and/or cover of the fixation device. Ceramic materials such as, for example, hydroxyapatite, bioglass, etc., may also be used for the fabrication of the system described herein. Of course, any combination of materials may be used to fabricate the entire fixation system described herein as well as the various components of the fixation system herein. Any and all such combinations of biocompatible materials are envisioned as being within the scope of the disclosure herein.

Referring now to figures 1-5, the bone fixation system disclosed herein will be described. The fixation system depicted in figure 1 comprises cover 1 and elongated plate 20 having a central longitudinal axis, opposed upper and lower surfaces and an outer periphery. The outer periphery of the plate body is defined in part by opposed first and second lateral edges. The opposed first and second lateral edges are preferably curved inward toward the longitudinal axis in a medial region of the plate. These curvilinear portions 21 are generally to minimize rubbing contact that may occur between the plate and adjacent body tissues, e.g., blood vessels.

Cover 1 includes protrusions 10 on the inside that fit, snap, etc., into through-bores or screw holes 25 of plate 20 having proper configurations which accept screws (not shown) to anchor elongated plate 20 to the bone (not shown). The screw holes can be configured to allow for dynamic motion of the plate relative to the bone, e.g., oblong, or configured to provide for fixed attachment of the plate to the bone, e.g., circular with counter-bore or counter-sink configurations, etc. In this embodiment, cover 1 is engaged with elongated plate 20 by sliding the cover 1 onto the plate 20. The cover 1 is retained in place by the placement of a dovetail region 24 on at least a portion of the outer periphery of the plate 20. Depicted in figure 1a is the fixation system herein with the cover 1 in place on the plate 20. As depicted in figure 1a, the protrusions 10 on the inside of cover 1 engage the screw holes or through-bores 25 of the plate 20. In this embodiment, the cover 1 abuts a ledge 26 located on top of plate 20 which facilitates alignment or mounting of the cover 1 to the plate 20 during the assembly.

The embodiment represented in figures 2 and 2a shows the combination of a dovetail region(s) 24 combining with protrusions 10 engaging with the screw holes 25 of plate 20 to result in a system wherein the separate points of fixation 10, 24, 25 supplement each other in maintaining the attachment of the cover 1 to the plate 20.

Figures 3 and 3a represent yet a further embodiment of the fixation system herein. In this embodiment, cover 1 contains side portions 4 that extend to the anterior or bottom surface of cover 1 and may contain protrusion(s) and/ grooved region(s) 5 that engage with corresponding features on the outer periphery 21 of the plate 20. As shown in figure 3a, the top and/or bottom surfaces 29 of the plate 20 are not contacted by the plate cover 1.

Figures 4 and 4a represent a further embodiment of the fixation system

described herein wherein the cover 1 contains side portion(s) 4 that extend below the anterior or bottom surface of the cover 1 and contain protrusion(s) and/ grooved region(s) 5 that engage with corresponding features on the outer periphery 21 of the plate 20. In this embodiment, the cover 1 also contains an end portion 9 that extends
5 to the anterior surface of the cover 1 such that when contacted with the plate 20 as shown in figure 4a, the top and/or bottom surfaces 29 of the plate 20 are contacted by this portion of the plate cover 1.

The embodiment disclosed in figure 5 is a bore cover 30 that is dimensioned to fit inside the screw hole 24 of the plate 20. As shown in the enlarged sectional view
10 of figure 5a, the bore cover 30 of this embodiment frictionally or forcedly fits inside of the screw hole 24 so that it is flush with the outer surface of the plate 20.

Figure 6 represents an alternative embodiment of the fixation system. A bore cover 40 includes a cover plate 42 of circular configuration, tab portions 44 disposed at outer portions of the cover plate 42, and a tool engaging hole 46 for mounting the
15 cover 40 to the plate 20. The plate 20 is similarly configured to receive the bore cover 40 within a through-bore 24a which includes corresponding tab receiving portions 24b and glove portions 24c for engaging the tab portions 44 of the bore cover 40 upon rotation thereof and thereby preventing the bore cover from disengaging therefrom. Reference "S" illustrates the head portion of a screw engaged with the plate 20
20 through the bore 24a and thereby attached to the bone (not shown).

Figure 7 represents another alternative of the fixation system. A bore cover 50 includes a cover plate 52 of circular configuration, a circumferential bead portion 54 disposed around the circumference of the cover plate 52, and a tool engaging hole 56 for mounting the cover 50 to the plate 20. The plate 20 is similarly configured to

receive the bore cover 50 within a through-bore 24d which includes a corresponding bead receiving groove 24e for receiving the circumferential bead portion 54 of the cover plate 52 by, e.g., snug fit, friction fit, or press fit through the through-bore 24d. Upon engagement, these arrangements provide resistance from disengagement of the cover 50 from the plate 20 and thus prevent from "backing out" of the screw used to attach the fixation system to the bone (not shown).

In yet a further embodiment, provided is a method of using the fixation system described herein. Prior to fixation of the plate 20 to a bone, preferably an anterior portion of a vertebra, the cortical surface of the bone is shaped in some manner, e.g., machining, to provide an appropriately shaped recess to receive the fixation system. In this manner, when the fixation system is fixed to the bone, some, most, or all of the fixation system is contained within the appropriately shaped recess to minimize any portion of the fixation system being above the surface of the bone.

Further embodiments of the fixation system disclosed herein will be apparent to those having skill in the art in view of the specification and accompanying figures. For example, the covers 30 could be threaded so that they could be screwed into appropriately threaded screw holes 24. Moreover, other techniques not disclosed herein may be used to secure the cover to the plate. For example, besides dovetail connectors, tongue and groove connectors may also be used as well as a friction fit connection.

Although the invention has been described and illustrated with respect to the exemplary embodiment thereof, it should be understood by those skilled in the art that

the foregoing and various other changes, omissions, and additions may be made therein and thereto, without parting from the spirit and scope of the present invention.

WHAT IS CLAIMED IS:

- 1 1. A bone fixation system which comprises:
2 an elongated plate body having a central longitudinal axis, opposed upper and
3 lower surfaces and an outer periphery defined in part by opposed first and second
4 lateral edges, the elongated plate body including at least one through-bore formed
5 between the opposed upper and lower surfaces for receiving at least one respective
6 bone fastener to secure the elongated plate body to a bone repair site; and,
7 a lockable cover engageable with at least a portion of the upper surface of the
8 elongated plate body to cover at least a portion of the at least one through-bore
9 formed therein.

- 1 2. The bone fixation system of Claim 1, wherein the cover is configured
2 to cover substantially the whole upper surface of the elongated plate body when the
3 cover is engaged to the elongated plate body.

- 1 3. The bone fixation system of Claim 1, wherein the elongated plate body
2 and the cover include corresponding dovetail structures for the engagement with each
3 other.

- 1 4. The bone fixation system of Claim 3, wherein the cover includes at
2 least one protrusion to further engage with the respective at least one through-bore of
3 the elongated plate body.

1 5. The bone fixation system of Claim 3, wherein the elongated plate body
2 includes a ledge portion for facilitating alignment of the elongated body and the
3 cover.

1 6. The bone fixation system of Claim 1, wherein the cover includes at
2 least one protrusion to engage with the respective at least one through-bore of the
3 elongated plate body.

1 7. The bone fixation system of Claim 1, wherein the opposed first and
2 second lateral edges are curved inward toward the central longitudinal axis in a
3 medial region of the plate.

1 8. The bone fixation system of Claim 1, wherein the cover includes side
2 portions extending to the lower surface of the cover to at least partially enclose the
3 outer periphery of the elongated plate body.

1 9. The bone fixation system of Claim 8, wherein the side portions of the
2 cover include guide structures to facilitate the engagement of the cover with the
3 elongated plate body.

1 10. The bone fixation system of Claim 1, wherein the elongated plate body
2 and the cover are configured and dimensioned to conform the contour of the bone
3 repair site.

1 11. The bone fixation system of Claim 1 wherein the cover locks in place
2 by a friction fit.

1 12. The bone fixation system of Claim 1, wherein the cover locks in place
2 by a snap fit.

1 13. The bone fixation system of Claim 1, wherein the cover locks in place
2 by a key-and-slot fit.

1 14. The bone fixation system of Claim 1 wherein the elongated plate body
2 and/or cover are fabricated from a shape memory alloy.

1 15. A method of bone fixation which comprises:

2 a) providing a bone fixation system including an elongated plate
3 having a central longitudinal axis, opposed upper and lower surfaces and an outer
4 periphery, the elongated plate including at least one through-bore formed between the
5 opposed upper and lower surfaces, and a lockable cover engageable with the upper
6 surface of the elongated plate to at least in part cover the at least one through-bore
7 formed therein.

8 b) accessing a bone repair site;

9 c) preparing or machining a recess at the bone repair site to such a
10 depth as to receive within the recess a substantial height of the elongated plate of the
11 bone fixation system;

12 d) fixing the elongated plate to the bone repair site by mounting at least

- 13 one fastener through the at least one through-bore of the elongated plate; and,
- 14 e) engaging the cover with at least a portion of the upper surface of the
- 15 elongated plate.

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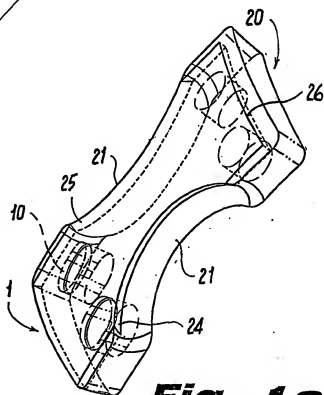
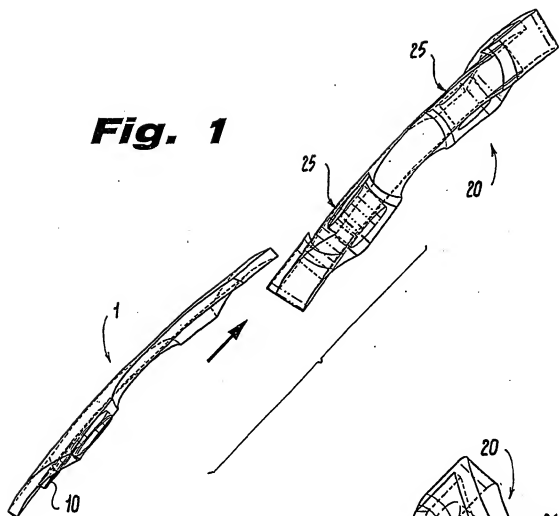
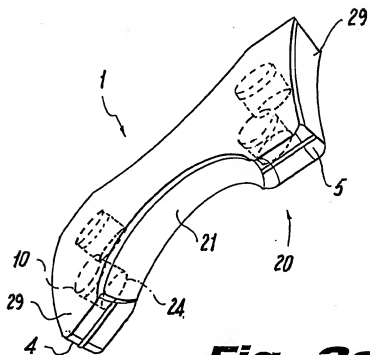
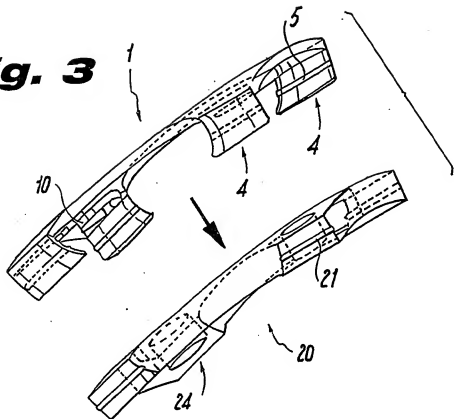
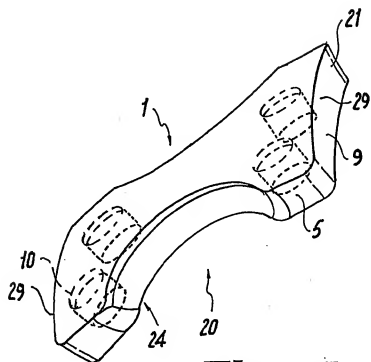
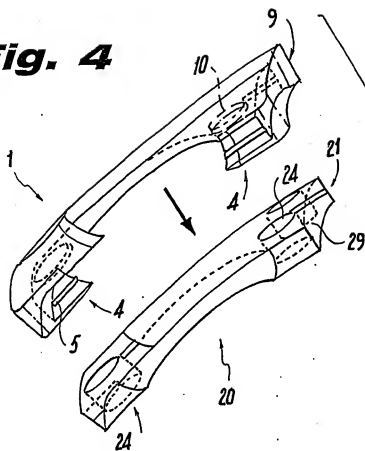
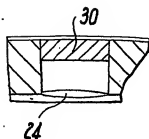
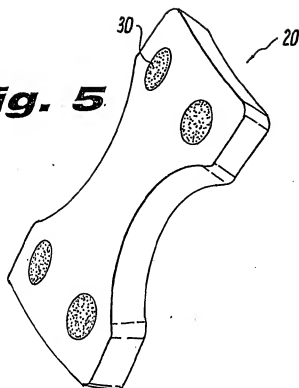
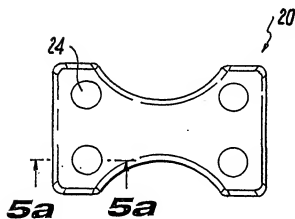
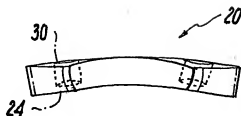
Fig. 1**Fig. 1a**

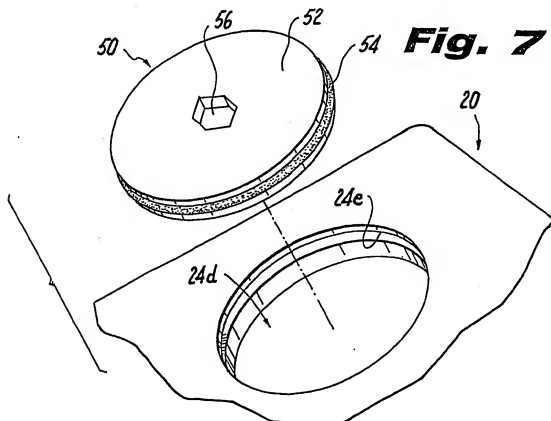
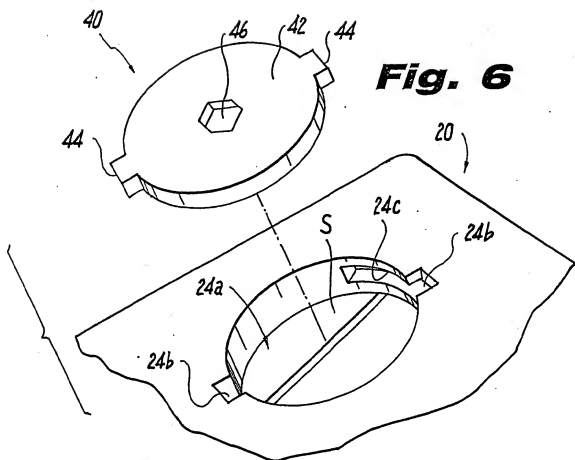
Fig. 3**Fig. 3a**

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Fig. 4**Fig. 4a**

5/6

Fig. 5**Fig. 5a****Fig. 5b****Fig. 5c**



INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 02/10683

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/70 A61B17/80

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 794 918 A (WOLTER DIETMAR) 3 January 1989 (1989-01-03) the whole document	1,2
X	US 5 766 254 A (GELBARD STEVEN D) 16 June 1998 (1998-06-16) the whole document	1,2
X	FR 2 740 321 A (FUENTES JEAN MARC) 30 April 1997 (1997-04-30) the whole document	1,2,6
X	WO 99 21502 A (BRAY ROBERT S JR) 6 May 1999 (1999-05-06) the whole document	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
 E earlier document but published on or after the international filing date
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 Z document member of the same patent family

Date of the actual completion of the international search

25 July 2002

Date of mailing of the international search report

05/08/2002

Name and mailing address of the ISA

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Authorized officer

Verelst, P

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/10683**Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

The International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/10683

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			US	6235034 B1	22-05-2001

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